Claims

1. A pharmaceutical oral controlled release composition comprising 10,11-dihydro-10-hydroxy-5H-dibenz[b,f]azepine-5-carboxamide.

2. The pharmaceutical composition according to claim 1 being a disintegrating tablet with modified release granules comprising 10,11-dihydro-10-hydroxy-5H-dibenz[b,f]azepine-5-carboxamide.

3. The pharmaceutical composition according to claim 2 wherein the 10,11-dihydro-10-hydroxy-5H-dibenz[b,f]azepine-5-carboxamide is present in the granules in an amount of from 60 to 90 % by weight of the modified release granules.

4. A pharmaceutical composition according to claim 2 or 3 comprising 10,11-dihydro-10-hydroxy-5H-dibenz[b,f]azepine-5-carboxamide having a median particle size between 150 and 300 μm.

5. A pharmaceutical composition according to any one of claims 2 to 4 wherein the modified release granules comprise as retarding agent at least one polymer selected from polymethacrylates, ethylcellulose, hydroxyethylcellulose, hydroxypropylcellulose and methylcellulose.

6. A pharmaceutical composition according to claim 5 comprising polymethacrylates and ethylcellulose wherein the polymethacrylates are present in the granules in an amount of 5 to 25 % by weight of the modified release granules.

7. A pharmaceutical composition according to claim 5 or 6 comprising polymethacrylates and ethylcellulose wherein the ethylcellulose is present in the granules in an amount of from 2 to 10 % by weight of the modified release granules.

8. A pharmaceutical composition according to any one of claims 1 to 7 comprising 10,11-dihydro-10-hydroxy-5H-dibenz[b,f]azepine-5-carboxamide in an amount of from 50 to 80 % by weight of the total composition.

9. A pharmaceutical composition according to any one of claims 1 to 8 comprising microcristalline cellulose.

10. A pharmaceutical composition according to any one of claims 1 to 9 comprising at least one natural starch as disintegrant.

11. The pharmaceutical composition according to claim 10 comprising maize starch as disintegrant.

12. A pharmaceutical oral controlled release composition comprising 10,11-dihydro-10-hydroxy-5H-dibenz[b,f]azepine-5-carboxamide, wherein in use 70 to 90 % of said 10,11-dihydro-10-hydroxy-5H-dibenz[b,f]azepine-5-carboxamide are released within 6 hours indicated in standard in-vitro dissolution tests at 37°C in phosphate buffer having a pH of about 6.8 for a 500 mg dosage form.

13. The pharmaceutical oral controlled release composition comprising 10,11-dihydro-10-hydroxy-5H-dibenz[b,f]azepine-5-carboxamide according to claim 12, wherein in use 80 to 90 % of said 10,11-dihydro-10-hydroxy-5H-dibenz[b,f]azepine-5-carboxamide are released within 6 hours indicated in standard in vitro dissolution tests at 37°C in phosphate buffer having a pH of about 6.8 for a 500 mg dosage form.

14. A pharmaceutical oral controlled release composition according to any one of claims 1 to 13 having no food effect.

15. A disintegrating tablet having modified release granules comprising 10,11-dihydro-10-hydroxy-5H-dibenz[b,f]azepine-5-carboxamide and at least one polymer as retarding agent adapted to be administered once a day.

16. The disintegrating tablet according to claim 15 wherein the at least one polymer is selected from polymethacrylates, ethylcellulose, hydroxyethylcellulose, hydroxypropyl-cellulose and methylcellulose.

17. A disintegrating tablet according to claim 15 or 16 having no food effect.

18. A pharmaceutical oral controlled release composition comprising 10,11-dihydro-10-hydroxy-5H-dibenz[b,f]azepine-5-carboxamide displaying a plateau profile between about 4 and 25 hours after administration.

19. Use of 10,11-dihydro-10-hydroxy-5H-dibenz[b,f]azepine-5-carboxamide and excipients as defined in any one of claims 1 to 18 for the preparation of a medicament for the treatment of patients with affective disorders.

20. A method of orally administering 10,11-dihydro-10-hydroxy-5H-dibenz[b,f]azepine-5-carboxamide for the treatment of affective disorders, said method comprising orally administering to a patient in need of 10,11-dihydro-10-hydroxy-5H-dibenz[b,f]azepine-5-carboxamide therapy once a day a pharmaceutical composition according to any one of claims 1 to 18.